REMARKS

Claims 1-13 are pending. No new matter has been added by way of the present amendment. For instance, the amendment made to claim 3 deletes 2-methylbenzaldehyde and inserts 1-naphthaldehyde as supported by the present specification, for instance reference is made to Example 6 at page 13, line 2 of the present specification. Typographical errors have also been corrected in claims 1 and 5. New claims 12 and 13 are supported by the present specification, for instance, at page 5, line 21 to page 6, line 9. Additionally, a sentence at page 8, lines 4-6 of the present specification has been clarified. Support for this amendment may be found in originally filed claim 9. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdrawal all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-11 under 35 U.S.C. §103(a) as being obvious over Hong, U.S. Patent No. 5,869,670 (Hong '670) in view of Khomutov et al., Tetrahedron Lett., 42:2887-2889 (2001) (Khomutov). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that claims 1-11 are unpatentable over Hong '670 in view of Khomutov et al. since the technical constitution of the present invention could allegedly be conceived by combining the synthesis process of Gemifloxacin disclosed in Hong '670 with the use of benzaldehyde as a primary amine protecting group disclosed in Khomutov. However, significant patentable distinctions exist between the present claims and Hong '670. These distinctions are far in excess of any supplemental disclosure of Khomutov.

For instance, the synthesis process of Gemifloxacin disclosed in Hong '670 essentially comprises a step for recrystallizing Gemifloxacin acid salt to remove impurities. Thus, the overall yield of Gemifloxacin according to Hong '670 cannot but be reduced due to the recrystallization step. Applicants point out that most of the yields in the examples of Hong '670 are in the range of about 40 to 70% and the maximum yield is 87% only.

In the present invention, however, recrystallization of Gemifloxacin can be omitted by using a compound of the specific structure (formula 5) as a primary amine protecting group in the step for synthesizing Gemifloxacin. Consequently, the overall yield of Gemifloxacin is significantly higher according to the present invention, compared with Hong '670. Applicants note that all the yields in the Examples of the present invention are in the range of about 80 to 95%.

Also, in the present invention, deprotection and preparation of Gemifloxacin salt are carried out in a single step of preparing Gemifloxacin acid salts. This is not disclosed in either Hong '670 or Khomutov.

Therefore, the method for preparing gemifloxacin acid salts of the present invention, wherein the step for recrystallizing Gemifloxacin is omitted, and deprotection and preparation of Gemifloxacin salt is carried out in a single step, is clearly different from the synthesis process of Gemifloxacin comprising three steps disclosed in Hong '670. Thus, no *prima facie* case of obviousness exists. Moreover, the present invention has distinctively advantageous effects over Hong '670 in terms of yield of the target product and simplicity of the process. These results are unexpected and thus rebut any hypothetical *prima facie* case of obviousness. To summarize, there exists no motivation in either Hong '670 or Khomutov to pursue the present invention. The

above distinctions remain even if the synthesis process of Gemifloxacin disclosed in Hong '670 is combined with the use of benzaldehyde as a primary amine protecting group disclosed in Khomutov.

Accordingly, Applicants respectfully submit that significant patentable distinctions exist between the present claims and the cited art. Accordingly, there exists no *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection is respectfully requested.

Obviousness-Type Double Patenting

The Examiner has rejected claims 1-11 under the judicially created doctrine of obviousness-double patenting as being obvious over claims 1 and 2 of Hong '670 in view of Khomutov. Applicants respectfully traverse this rejection. As explained above, Applicants have distinguished claims 1-11 from the cited art. Accordingly, there exists no obviousness-type double patenting over the combined references of Hong '670 and Khomutov. Thus, this rejection is improper and should be withdrawn.

In view of the above, Applicants respectfully submit that the present claims define subject matter which is allowable. Accordingly, the Examiner is respectfully requested to withdrawal all rejections and allow the currently pending claims.

REQUEST FOR INITIALED INFORMATION DISCLOSURE STATEMENT

On October 7, 2004, Applicants filed an Information Disclosure Statement with an attached PTO/SB/08A/B. However, the Examiner has not yet returned an initialed copy of this form indicating that the cited references have been considered. Accordingly, the Examiner is

respectfully requested to return an initialed copy of the form which accompanied the October 7, 2004 IDS.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: May 23, 2006

Respectfully submitted,

By _____ #42,874

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